Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

DATE: September 28, 2009

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Manager, Food Protection Program

SUBJECT: Philips Recall

SUGGESTED ACTION: **Unclassified Recall; Heartstart Fr2+ Automated External Defibrillators; An advisory being sent in case of user inquiry.**

From the information provided by FDA, the product being recalled was distributed in the State of Indiana. The AEDs affected by this recall have been distributed globally to fire departments, emergency medical services, hospitals, and other organizations.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Philips Issues Worldwide Recall of Select Heartstart Fr2+ Automated External Defibrillators

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FOR IMMEDIATE RELEASE - September 28, 2009 - Seattle - Philips announced today that it is voluntarily recalling approximately 5,400 HeartStart FR2+ automated external defibrillators (AEDs). This recall is being conducted due to the possibility of a memory chip failure that may render the device inoperable. Only certain HeartStart FR2+ AEDs (models M3860A and M3861A, distributed by Philips; and models M3840A and M3841A, distributed by Laerdal Medical) manufactured between May, 2007 and January, 2008 are included in the voluntary recall.

The HeartStart FR2+ defibrillators are used by trained responders and designated response teams to help treat sudden cardiac arrest. The device automatically analyzes the heart rhythm and determines whether a defibrillation shock is needed. If a shockable rhythm is detected, the FR2+ instructs the responder to deliver defibrillation therapy.

Philips has received reports of a memory chip failure in a small number of FR2+ units manufactured in 2007 and early 2008. These reported failures were detected during routine self tests, not during emergency use of the AED. Failure of this chip could render the AED inoperable and prevent it from delivering therapy when indicated, although Philips has received no reports of injury associated with this chip failure.

The AEDs affected by this recall have been distributed globally to fire departments, emergency medical services, hospitals, and other organizations. Philips is contacting customers to arrange for the return and replacement of all the recalled AEDs by sending notification letters to distributors and users. In addition, the company has set up a page on the Philips Web site with a serial number look-up tool to allow customers to find out if their FR2+ is part of this recall, as well as instructions on what to do if it is. The Web page is www.philips.com/FR2PlusAction.

Philips has notified the U.S. Food & Drug Administration (FDA) of its decision to voluntarily recall the affected product. Customers who have questions about the recall or wish to report product problems may contact HeartStart Customer Service at 1-800-263-3342.

Any adverse events experienced with the use of this product should be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch Web site at www.fda.gov/medwatch.